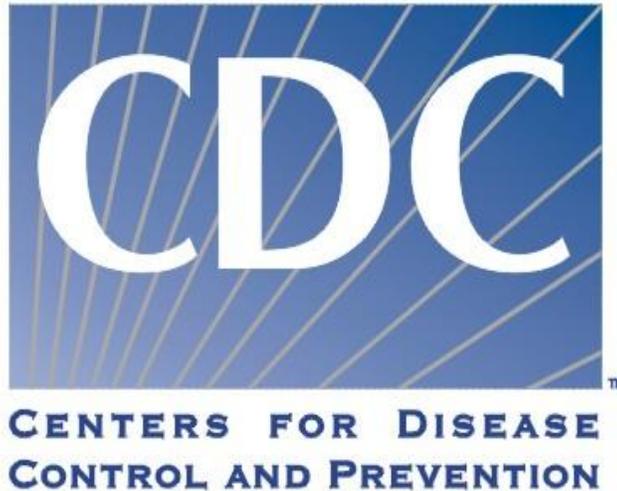


**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION/
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY**



**Joint Meeting of the
Ethics Subcommittee of the
Advisory Committee to the Director, CDC
and the
CDC Public Health Ethics Committee
February 18-19, 2010**

Minutes

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Acronyms Used in This Report

ACD	Advisory Committee to the Director
APHA	American Public Health Association
CDC	Centers for Disease Control and Prevention
HHS	Department of Health and Human Services
IHRs	International Health Regulations
MMRV	Measles, Mumps, Rubella Vaccine
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Report</i>
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
OCSO	Office of the Chief Science Officer
OMB	Office of Management and Budget
OSLS	Office of State and Local Support
OWCD	Office for Workforce and Career Development
PHEC	Public Health Ethics Committee
SMEs	Subject Matter Experts

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Agency for Toxic Substances and Disease Registry

JOINT MEETING OF THE
ETHICS SUBCOMMITTEE OF THE
ADVISORY COMMITTEE TO THE DIRECTOR, CDC
AND THE
CDC PUBLIC HEALTH ETHICS COMMITTEE
February 18-19, 2010
Atlanta, Georgia

Minutes of the Meeting

Thursday, February 18, 2010

Introductory Remarks and Overview of Meeting Goals

Robert Hood, PhD
Chair, Ethics Subcommittee

At 1:07 PM, Dr. Robert Hood called the joint meeting of the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC) and CDC's Public Health Ethics Committee (PHEC), to order. He invited members to introduce themselves (see Attachment 1 for list of meeting attendees) and to declare any conflicts of interest. No conflicts were identified. Dr. Hood reviewed the meeting agenda and goals, which were as follows:

- Provide update on status of ongoing Ethics Subcommittee activities
- Provide update on ongoing CDC public health ethics activities
- Review recent changes at CDC and discuss implications of these changes for the Ethics Subcommittee activities
- Plan future direction for the Ethics Subcommittee

Update: Status of Ongoing Ethics Subcommittee Activities

Drue Barrett, PhD
Designated Federal Official, Ethics Subcommittee

Dr. Drue Barrett provided an overview of the status of the Ethics Subcommittee's on-going activities. The three key areas reviewed included:

- Ventilator Guidance Document
- Travel Restriction Workgroup

- Emergency Preparedness and Response Guidance

Concerning the Ventilator Guidance Document, the following points were made:

- Current and former members of Ethics Subcommittee working on the document include Bernard Lo, Robert Hood, Kathy Kinlaw, and Robert Levine
- The Guidance was approved by the Ethics Subcommittee on November 23, 2009
- There are minor revisions being made to address comments made during the November meeting
- The Guidance is currently waiting for review and approval by the Advisory Committee to the Director (ACD)
- The ACD is scheduled to meet on April 12, 2010

Dr. Barrett also noted that beyond the approval of the ACD, the Guidance document must then be sent to the Department of Health and Human Services (HHS), which will have 30 days to comment, after which time the document will be considered officially approved. This process can present difficulties with expediency.

Concerning the Travel Restriction Workgroup, which addresses the use of new tools for restricting travel of people with infectious diseases, the following information was presented:

- Members of Ethics Subcommittee on the Travel Restriction Workgroup include Kathy Kinlaw, Vanessa Gamble, and Robert Levine
- A guidance document on ethical considerations for using travel restrictions tools was approved by the Ethics Subcommittee on April 7, 2009 and by the ACD on September 1, 2009
- The guidance will be included in a CDC Standard Operating Procedure (SOP) document on use of the travel restriction tools. One of the target audiences for the SOP are field staff at quarantine stations who will be on the front line for implementing the travel restriction tools.

Dr. Barrett elaborated on “Ethical Considerations for Use of Travel Restriction Tools,” which focuses on how to best use these tools while protecting individuals rights. The key considerations include the following:

- Protecting community interests while respecting individual rights
- Proportionality
- Social and distributive justice
- Beneficence
- Transparency and clear communication
- Maximize preparedness; work collaboratively
- Global responsibility
- Respecting individuals’ privacy while protecting community

The Travel Restrictions Workgroup’s next steps are to use the workgroup as a forum for discussing “real-world” issues resulting from the implementation of travel restriction tools. A workgroup meeting has been scheduled for February 26, 2010. During this meeting, the workgroup will review specific cases of use of travel restrictions which raised ethical concerns in order to provide guidance that can be used for addressing future cases.

In regard to the *Ethical Guidance for Public Health Emergency Preparedness & Response* document, the primary authors of the White Paper are Bruce Jennings, Center for Humans and Nature, and John Arras, University of Virginia. The document is in the process of being prepared for publication as a special supplement in the *Morbidity and Mortality Weekly Report (MMWR)*, with production time estimated at 13 weeks, or midsummer for publication.

In addition to the White Paper the MMWR supplement will include focus papers written on leading experts on the following topics:

- Research during Public Health Emergencies*, Alex Jon London, Carnegie Mellon University
- Vulnerable Populations*, Madison Powers, Georgetown University
- Justice, Resource Allocation and Stockpiling*, Norman Daniels, Harvard School of Public Health
- Professional, Civic and Personal Obligations*, Angus Dawson, Keele University
- Community Consultation*, Ruth Gaare Bernheim, University of Virginia

Dr. Barrett also provided a summary of some of the current activities of PHEC, which include:

- Development of ethics guidance for human genomics studies
- Release of a Web-based public health ethics training
- Survey of CDC staff on public health ethics
- Development of internal public health consult procedures
- Development of regional public health ethics consortium

Dr. Barrett mentioned in conclusion that the day before, February 17, 2010, Bruce Jennings, Ruth Gaare Bernheim and others conducted a panel presentation on ethical issues in emergency preparedness and response at the Public Health Preparedness Summit. There was considerable interest in the topic as demonstrated by the standing room only crowd. .

Summary of Discussion

Some concern arose over the length of time required to produce the various documents, specifically anything that is considered to be a product of the Ethics Subcommittee. These documents must go through a lengthy approval process, crossing several desks before reaching the public, which raises the question of efficacy in terms of timeliness. Discussion of individual cases, on the other hand, does not require the process of approval. The White Paper, as an example, took several years to produce.

Update and Discussion: Genomics Best Practices Guidance

Sara Giordano, PhD
Ethics Project Coordinator, McKing Consulting
Office of Public Health Genomics

Dr. Giordano provided an overview of work being done to develop ethics guidance for human genomics studies. This included work she had done on reviewing CDC protocols involving collecting of human Genetic data in order to assess current practices relating to informed consent, returning research results, and future use of data. The main project goals are to:

- Collect and analyze data from all research protocols and consent forms from currently active CDC IRB-approved studies involving human genomics;
- Summarize practices, with a focus on human protection. As a result the consent forms were of particular interest; and
- Develop a guidance document that will be useful for both researchers and IRB members who conduct and review human genomics research studies. There is currently a lack of information in this area.

Dr Giordano presented an outline of the proposed guidance document. The scope of the document will apply ethics to all aspects of genomics research. The outline appears as follows:

I. Introduction

- Purpose and approach
- Summary of current practices based on project
- Public Health Ethics
- Public Health Genomics

II. Conducting public health Genomic Research

- Designing protocol / research project
- IRB Submission and Review
- Recruiting Subjects
- Consent Process
- Conducting experimental data collection
- Data analysis / data sharing
- Reporting results
- Storage of specimens for future research

Dr. Giordano's presentation focused on her findings regarding returning research results, with specific focus on the following:

- Which results should be returned?
 - Group or individual results?
 - Clinically relevant, significant, useful?
 - When and by whom should this be determined?
- How should results be returned?
 - Through mail or in person?
 - Should genetic counseling be available?
- To whom should results be returned?
 - Participants, doctors, family members?
- Should participants have a right to know their results?
- Should genetically related persons have any right to know?

- ❑ Should participants have the right *not* to know? There is at least a clear consensus on the situation in which a patient does *not* want results returned. The consensus is that this is acceptable and does not pose a problem.

In summarizing the range and scope of the ethical debate on returning samples, decision-making was influenced by three different schools of thought:

- ❑ “Anonymize” samples: the move to make it impossible to return results through anonymity when contact information is removed
- ❑ Context specific: the type of research, who the participants are, who the researchers are will affect the decision
- ❑ Return all results:
 - Defining “all results” remains a question - are they actual results, do they need to be peer-reviewed
 - Return all group results and return individual results if they are deemed useful.

A summary of current practices at CDC concerning returning results was presented. In regard to the inclusion of information in consent forms about returning results in the following was found:

- 29/43 (67%) discuss returning *individual* results
- 6/43 (14%) discuss returning *group* results
- One study has different consent forms for different sites and it depends on the form/site.

A breakdown of studies which address returning results in consent forms:

- 12/29 (41%) studies state that they will not return any results to participants
- 17/29 (59%) studies at least leave open the possibility

Dr. Giordano also relayed her interest in the idea of returning group results and maintaining conversation with study subjects through an internet newsletter or some other form of media. This type of ongoing communication would have study participants more involved and would avoid problems associated with returning clinical results which are of undetermined value and potentially harmful. Concerning group results, Dr. Giordano stressed the importance of returning both positive results and negative results. She also pointed to the need to consider how good practices and guidelines can be developed when dealing with diverse research in order to avoid recommendations that are too vague or too specific.

Summary of Discussion

In addressing the process of reviewing studies for guidance on returning results, it was suggested that the focus be on existing procedures or policies in other models. The direction people are moving in is to cast DNA data as a public resource, which is beneficial as it moves away from genetic determinism. Studies that are based on a bio-banking model, conducted as a census or a genealogy study, are possible models for returning results. There is a tradition at CDC of returning clinical results that may *benefit the patient*. The model of returning clinically useful results may be relevant to genomics. However, it was noted that there is a significant

difference in comparing clinical results research with genetics research. For example, a key difference exists in the case of changing data versus un-changing data, where a set of information that remains consistent throughout a patient's lifetime (DNA data) that is not currently useful may become useful at a future date. Another challenge exists in regard to the benefit of returning results when a patient may not have the education to interpret them.

A request was made for the Ethics subcommittee to review and provide feedback on the Guidance document as it is developed.

Update and Discussion: Web-based Public Health Ethics Training

**Daniel McDonald, PhD, Team Leader
Public Health and Preparedness Training Team
Human Capital Management Office (Proposed)**

Dr. McDonald presented an overview of the online course in development. His former office wanted to develop a web-based foundational course on public health ethics. The office monitors competencies in mission critical employees and develops training to address gaps in public health knowledge. However, in attempting to provide sufficient training, some difficulties arise. Only about 60% of employees are in Atlanta and it is often impractical for many employees to attend in person trainings. The proposal is to create a series of online courses related to public health knowledge. Public health ethics is a good foundational place to start toward that effort. This course may also benefit employees who cannot afford costly trainings.

The online course is comprised of 10 lessons, divided into 3 modules:

Module 1: Basic Concepts of Public Health

- Definition of public health ethics
- Organizational benefits of public health ethics
- Public health ethics and clinical ethics
- Ethical theories
- Public health values
- Public health principles

Module 2: Public Health Ethics In Action

- Making hard choices
- Multiple perspectives

Module 3: Public Health Ethics at CDC

- CDC public health ethics infrastructure
- CDC public health ethics resources

Module 2 presents the trainee with interactive learning opportunities, different scenarios, and other perspectives, which can provide an engaging learning experience. Module 3 is being affected by the current restructuring at CDC and is undergoing adjustments accordingly. With respect to implementation, the course has gone through all CDC clearance procedures. After

last minute clarifying of CDC infrastructure, the program will be available to employees in March 2010.

Dr. McDonald's team provides many integrated, blended learning activities. The public health Preparedness Certification Course, which is offered to both employees and representatives from the Ministries of Health in other countries, is an immersive course culminating in 40 hours of faculty lead training. The online portion of this course could potentially include the ethics component as a pre-requisite for this certification program.

The Public Health Administration Curriculum could also incorporate the online ethics course as one of its offerings, integrating it as a pre-requisite course for employees who wish to seek more advanced training. While developing a competency model for an emerging entity, the CDC Health Policy Institute, ethics emerged as a relevant component in this model and will be included in the curriculum. The training will be made available to collaborating federal departments as well.

Summary of Discussion

The final version of the on line ethics course will be accessible on a learning portal. The course is designed to be a basic introductory course that CDC staff can take in a relatively short amount of time, and will most likely be a voluntary course. In discussing the next steps for more advanced training, one possible topic could be providing guidance in the realm of public engagement. This course may also be relevant to the workforces of state and local health departments, and could eventually be made available on www.train.org to any public health workforce employee worldwide.

Lisa Lee, Office of the Chief Science Officer (OCSO), added that CDC has recently been given permission to incorporate a mandatory training module on research ethics for all scientists at CDC, and a new requirement for human subjects research training every three years. These trainings will be made available to the non-scientific staff as well.

CDC employees have individual learning accounts they use to bring in subject matter experts (SMEs) and organize trainings on subjects of interest, such as public engagement. This appears to be becoming a more common practice among staff.

Update and Discussion: Survey of CDC Staff, CDC Public Health Ethics Consultation Process, and Public Health Ethics Consortium

Drue Barrett, PhD
Designated Federal Official, Ethics Subcommittee

Staff Survey

Dr. Drue Barrett discussed the upcoming CDC staff survey on public health ethics. A copy of the survey was provided to Ethics Subcommittee members. The survey should provide information on:

- Value and usefulness of public health ethics for CDC staff member's work

- Baseline understanding of public health ethics
- Skills in applying public health ethics
- Knowledge of CDC's public health ethics activities—degrees of usefulness and value added
- Interest in training on public health ethics

The survey is scheduled to be rolled out on March 1, 2010 and will be available for at least 2 weeks.

An article will be posted on CDC's intranet site (CDC Connects) on around mid-March. The article will describe the public health ethics activities and introduce the upcoming online course. The course will be live the following week (by March 22, 2010).

CDC Public Health Ethics Consultation Process

The internal committee, PHEC, has developed procedures for conducting public health ethics consultations and established a Consultation Subcommittee. In addition, National Centers are encouraged to create their own public health ethics teams. There has been varying amounts of success in establishing such teams across the various centers. The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) has, for example, created a very robust team that meets frequently. Other centers have created teams that meet as needed.

The consultation procedures involve the following steps:

Phase 1: Identify

1. Identify the issue and gather information
2. Identify stakeholders and their values
3. Clarify question

Phase 2: Analyze

4. Evaluate information
5. Consider ethical perspectives
6. Critically weigh all factors

Phase 3: Resolve

7. Identify alternative
8. Weigh options
9. Develop recommendation

Some areas in which the consult team has been asked to offer guidance include male circumcision, MMRV vaccine, smallpox vaccine strategy, and returning mental health survey data.

Traditionally, PHEC receives three to four consult requests per year, but interest in the service appears to be increasing. Two consult requests were received this month. Raising awareness of the consult service and demonstrating its usefulness is key to ensuring success. However, an increase in demand also raises a concern about time management and resource limitations.

Public Health Ethics Consortium

An initial planning group has been convened comprised of Kathy Kinlaw, Emory University; Robert Hood, Florida Department of Health; Ralph Didlake, University of Mississippi Medical Center; and Leonard Ortmann, Tuskegee University. This planning group seeks to address the need for greater awareness of public health ethics in the region, and possibly nationwide. Dr. Bruce Jennings will also be invited to join the group. There is a need to identify appropriate specific goals for this consortium, which will primarily focus on information sharing and education. One idea is to develop case studies that addressing ethics concerns of state and local health departments.

Discussion: Future Direction for Ethics Subcommittee

Dr. Robert Hood, Florida Department of Health

Dr. Hood began the discussion by noting that because of the recent change in leadership, CDC is placing a greater emphasis on demonstrating the effectiveness of its on-going public health practice activities. Some high points of the new director's strategic directions are to strengthen surveillance and epidemiology of core public health services; support state and local health departments; improve CDC's global health efforts; develop CDC's leadership efforts in policy; and effectively address the burden of disease. Dr. Hood suggested that the Ethics Subcommittee focus on work that can support these new strategic directions. Specifically, the subcommittee should develop a plan to provide ethics support and develop ethics capacity in state and local health departments, and develop the ability to measure the effectiveness of public health ethics. CDC should identify the ethics needs of state and local health departments, keeping in mind the variability in how public health is organized in different jurisdictions.

Ruth Gaare Bernheim pointed to recent preparedness efforts with H1N1 and her years of experience working with local and state health departments to operationalize ethics. She suggested that there is a need to devise methods to integrate ethics into the actual practice management of local and state departments. It fits in nicely with an increased demand for accreditation and measurement. The issue of public engagement and community consultation in emergency preparedness benefits from a focus on ethics in terms of establishing the goals of community engagement, the appropriate methods and measurement of outcomes, and the assessment of impact on the community. One option is for PHEC to launch a systematic evaluation of state and local departments to measure the results of community engagement conducted as part of the H1N1 response. Emergency preparedness is an essential public health service; in order to be successful it requires community engagement.

Public health is an essential service and, therefore, at its core is community engagement. The data from H1N1 as a case study can be used in a larger sense to evaluate how public health initiatives impact the community and how ethics can be overlaid on to this process. It is very important from an organizational standpoint to communicate to state departments of health what ethical principles state and then focus on how to measure whether an organization is integrating ethics into its management system.

The goals of public engagement should be context-specific, ranging from allowing the public an opportunity to determine services, education, or collaboration as a social engagement; or fulfilling the need for legitimacy on the part of leadership.. Applying the principles of ethics can affect how health departments decide what kinds of public engagement are appropriate and then how to measure the goals.

It is very important is to distinguish between the need and the goal. The public health community does not necessarily see a need for public engagement, viewing the process as a means to achieving credibility, but not acknowledging the benefit of assessing peoples' values. There may exist a need to educate the public health community regarding the need for public engagement. As an example, in the influenza arena and controversial area of autism and immunization issues, a conscious effort to assess the values of the public resulted in a shift in perspective.

In approaching the task of encouraging the public health community to integrate public engagement into their practices, the committee should also consider the following:

- What plans have succeeded previously? (Washington and Virginia are examples)
- Who *is* the public? How can issues of representation, equity, and fairness be addressed?
- What kinds of *specific* help can be offered?

Dr. Jennifer Prah Ruger suggested using public engagement as a means to influence public decision-making as a voluntary response. The public should be educated about the importance of incorporating an assessment of societal risks and benefits into the decision making process. It is a challenge to have this message come from the federal government due to the perception of some that government officials are not acting servants of the people. This issue may be avoided if the mandates come from a local Health Department Ethics Committee. Community Advisory Boards exist that could be a model for this.

In terms of future directions, a suggestion was made to have the Subcommittee assist with the development of a public health ethics casebook. Another potential future direction would be to have the Ethics Subcommittee assist with the development of a survey of state and local health departments in order to identify their major ethical concerns. In deciding upon future directions, the Subcommittee should consider CDC priorities and select tasks which can clearly demonstrate the value of public health ethics. To the extent possible future activities should avoid a focus on remote issues and instead focus on day-to-day need. We will also need to address available resources and time-management of Subcommittee members.

Concerning the issue of resources, questions were raised about seeking additional funding through grant mechanisms and use of CDC staff for assistance.

Summary of Discussion

The two main approaches for future activities were discussed:

- Employing a targeted focus, making sure to tailor the Ethics Subcommittee's actions to the specific needs of CDC
- Focusing on the broad topic of the role of ethics in public health.

It was noted that these two approaches are related and that both could be addressed by the Subcommittee. The Subcommittee will strive to keep its focus in line with CDC priorities. Along

with this task, it is important to further explore the role of ethics within public health practice and to find ways of communicating ethics within health agencies. Public engagement is obviously of great interest to the Ethics Subcommittee. Consideration should be given to how this interest can be applied to the needs of CDC.

Public Comment

At 4:19 PM on February 18, 2010 Dr. Hood called for public comment in person or on the telephone. There were no requests to make public comment.

With no further business posed or comments raised, the meeting was adjourned at 4:32 PM.

Friday, February 19, 2010

At 8:34 am, Dr. Robert Hood reconvened the Joint Meeting of the Ethics Subcommittee of the Advisory Committee to the Director (ACD) and the CDC Public Health Ethics Committee, confirming that Vivian Berryhill, the representative of the ACD, was present by telephone. He then introduced Dr. Peter Briss, the Acting Associate Director for Science, for a presentation about organizational changes at CDC and the Director's priorities.

Update and Discussion: CDC's Organizational Improvement Activities, CDC Director's Priorities, and the Future Direction for the Ethics Subcommittee

Peter Briss, MD, MPH Acting Associate Director for Science, CDC

Dr. Briss emphasized that the year in public health has been eventful, with changes in administration, the H1N1 pandemic influenza, the earthquake in Haiti, healthcare reform I, and numerous environmental challenges. It is a good time to think about strategies for addressing ethical issues and to be aware of the context of current events and to do things that actually make a difference in the real world. Consequential epidemiology is key when discussing the ethics of high priority issues for the CDC, such as enhanced chronic disease prevention, healthcare reform, and global health.

Dr. Thomas Frieden began as the new Director of CDC in June 2009. Dr. Frieden has five priorities for the agency: 1) surveillance and epidemiology; 2) state and local support; 3) policy; 4) global health; and 5) addressing burden effectively. CDC's primary focus is to use information to stimulate public health action, so surveillance and epidemiology are essential for providing information for action. States and localities are where the "rubber meets the road," so it is vital for CDC to provide useful support where action occurs. CDC wishes to improve upon the ability to provide information that will inform policy discussions, both directly health relevant (e.g., paying for healthcare) and other policies with indirect relation to health (e.g., school, transportation, and environmental policies). Global health and addressing the main causes of burden are also high priorities. Dr. Frieden has identified a set of topical priorities that address

the main causes of burden: tobacco (a leading cause of death), overweight/obesity (currently going in the wrong-direction), teen and other unintended pregnancies, hospital-associated infections, HIV, and motor vehicle occupant injuries.

Pandemic influenza presents an opportunity to reflect on CDC's effectiveness in applying functional priorities. Everyone in the public health sector has spent the last 12 months in a full sprint trying to react to this pandemic in an effort to minimize burden. While the pandemic was considered mild compared to the 1918 pandemic, it nevertheless resulted in 10,000 deaths. CDC spent a lot of time conducting surveillance and epidemiology, with thousands of CDC members from a variety of disciplines rushing to identify the virus, monitor its susceptibility to antiviral treatments, and disseminate information. In the past, CDC has been able to gather data on the success of vaccinations 18 months after the season. However, this year reports on vaccination coverage were being collected and distributed every week or two, which is an amazing transition. Surveillance and epidemiology were occurring in real-time, allowing CDC to quickly disseminate information on topics such as distributions of vaccines and provide guidance—a very impressive and exciting evolution.

In terms of state and local support, CDC disseminated scarce, life-saving technologies (e.g., vaccines, anti-viral medications). In response to the challenge of protecting people while minimizing social disruption (e.g., school closings), successful communication was key in improving results from the Spring to the Fall. Pandemics do not respect national boundaries, so this was also a complicated global effort. Specimen sharing and distribution of information concerning vaccine efficacy were models for speed and efficiency. International influenza collaborations were in place before the pandemic occurred, providing unprecedented amounts of virologic data. However, distribution of vaccine donations to poorer countries was disappointingly slow. While surveillance was a success story, pre-pandemic planning efforts were primarily focused on Asia, which did not help when the virus emerged in Mexico, where early detection could have allowed for earlier production of vaccines by up to two months.

Current topics of interest relating to pandemic response include:

- The 6-month lag in development of vaccines; this is currently being addressed, and many resources are being dedicated to this task
- Improving global distribution capacity
- Vaccine donation distribution issues
- Potential to integrate various disease detection systems The International Health Regulations (IHRs) and communication between nations, Benefit-sharing; the imbalance in favor of wealthier nations
- Public misperceptions of over-preparedness

Tobacco is another major issue, with over 5 million global deaths each year. A surveillance system in over 160 countries will help to focus strategies and resources. This is a good example of information for action. In regard to state and local support, better funding could result in fewer deaths. If all US states were to fund comprehensive tobacco control programs annually at CDC-recommended levels (between \$9 and \$16 per capita, \$3.7 billion nationally), in 5 years an estimated 5 million fewer people would smoke, preventing hundreds of thousands of premature deaths. There are many opportunities to launch policy intervention and monitor effectiveness, with the application of the Family Smoking Prevention and Tobacco Control Act which 1) restricts outdoor and retail advertising; 2) requires new and changed tobacco products be subject to FDA approval; 3) requires disclosure of ingredients and constituents; 4) enhances cigarette warning labels; and 5) removes candy flavoring from cigarettes.

Public health ethics in context is still an emerging area at CDC. As new disciplines merge with existing disciplines, the transition can present a challenge. Important milestones of progress include building infrastructure / capacity / demand, relationship building, and providing advice / guidance / consultation.

In terms of the focus of previous activities of PHEC, effective activities to date include the following:

- Providing guidance in response to specific CDC issues: male circumcision, MMRV vaccine, smallpox vaccine strategy, returning mental health survey data, and H1N1 response; and
- Development of the capacity of CDC staff to address ethical issues by providing training, developing center level public health ethics teams, and supporting consultation procedures.

Going forward, the Ethics Subcommittee and PHEC would be wise to take into consideration the changing context in which its work will be done. The current economic environment demands an increased attention to the value of projects and justification of expenditures. Improvement in technology also raises expectations for speed, transparency, and accessibility. In principle, ethics activities could enhance credibility, trust, participation, decision-making and behavior. The challenge lies in measuring effectiveness in these areas. Keeping in mind the need to align with institutional priorities and define and measure the value added, potential areas for enhancement include strategy, focus, speed, intramural presence, response to windows of opportunity, ability to show important results, state and local support (including better assessment of local needs), and communication. Of particular interest is the need to develop strategies to address major questions as they occur. There is also a need to address the challenge of communication across a variety of disciplines, creating a common language.

Summary of Discussion

The list of priorities was developed primarily within CDC. The main criteria for selection considered the level of burden, per the CDC mission mandate and scope.

The barriers to speed include:

- The bureaucratic process; the challenge of balancing workload in a very large organization
- A lack of resources; the speedy reaction time to last year's influenza pandemic was the result of an increase in available funds
- Technological progress; the emergence of the electronic medical record may offer more solutions in the future, but is still in development
- Cultural; a desire to maintain a good world reputation and respect can often result in considerable time spent discussing minor details of a major issue

Several models of ethics in practice are:

- Ethics desk in the CDC Emergency Operations Center
- The current internal public health ethics consultation program, which is becoming more efficient
- Within the Emergency Operations Center, there is a planning group, the Plans Decision Unit, that brings together experts who are asked to make recommendations regarding specific decision questions; this group includes a CDC ethics representative.

The process of building capacity is a good investment, but it takes time. CDC is focusing on several levels of capacity building, which include educational components, seminars, encouraging the integration of center public health ethics teams, encouraging teams to host trainings, and fellowship programs.

CDC expresses a strong commitment, even during the time of infrastructure transition, to address ethics issues and consider ethics in public health as a high priority.

Suggestions for approaches PHEC could take in terms of new directions:

- Create simple one-page consultations that help to identify dimensions of “hot button” issues so there is something in place in anticipation of ethical concerns
- Organize a Town Hall meeting at APHA about public health ethics
- Develop case studies as examples of ethics practices that influence decision making

There was agreement that it would be useful for the field to develop methods for measuring the impact of ethics on public health programs and policies. The value of ethics is often stated to be the impact it has on improving decision making and building credibility and trust. There is some benefit in first defining what constitutes a “better decision” as it applies to ethics. One model is to shift from evidence-based decisions to *values-aligned* decisions as the ideal. To truly define a values-based ideal, one must therefore involve the public. Emerging literature on empirical ethics evidence may inform this discussion further. The difficulty with balancing evidence-based and values-based decisions is that the two are often contradictory. In seeking to prioritize activities, it is recommended that the Ethics Subcommittee consider issues for which there is a better opportunity to influence an outcome of importance.

It may be productive to consider institutionalizing public consultation as an aspect of capacity building. This would require the development of an additional theoretical model for health communication. There is evidence of a shift in social culture wherein people want more say in the decisions that affect their lives (e.g., Wall Street banking crisis). However, the participatory process can have an adverse affect on speed. One argument suggests that a context-specific approach may be necessary to determine value, while the other view suggests that public consultation is a necessity and should be institutionalized.

Jennifer Prah Ruger elaborated on the topic of shared health governance as it compares to simple public participation. There is already a process of public participation in place, through the representational governmental structure. But beyond these organizational decisions, individual decisions are being made daily that have an impact on shared resources and on society. Infectious agents are a perfect example. It is critical to incorporate both experts and the public in the process of understanding that society has common objectives, and so a shared responsibility in governance can emerge. The concept of layering ethical social responsibility onto scientific decision-making remains a challenging one. CDC is presented with the challenge of finding a way to educate the scientific community on the importance of incorporating ethical practices in their decision-making processes, and of measuring the results of this influence.

Public consensus is necessary for decisions that require a trade-off between safety and liberty. An institutionalized process of public consultation on a larger scale would both fulfill this need while simultaneously providing public education opportunities.

Concerning building capacity for public consultation, one question that must be addressed is: In what areas should the public be involved? For example, in AIDS research design, the issue of

when outcomes should be made available to the population, and to whom, is considered a technical decision, but is of great concern to the public who would like to have a voice in the matter. There is a disparity in perception between science and science policy. Another question that must be addressed pertains to recognizing the need to assure fair representation among the public, and defining who the public is and how to engage different communities. The tradition of defining populations by attributes may be one cause of the inequity of representation. A better strategy to define representation is to focus on an individual's social network.

The argument against public consultation revolves around the concern that some issues are of a predominantly technical nature and that the public may not be well-informed enough to contribute effectively. Seeking a specific issue for which public consultation is the most effective tool with which to apply ethics practices may be a better direction than attempting to establish participation as a construct itself. An example of this method already exists in the work being done with influenza preparedness.

A variety of models for integrating public consultation have been suggested, and the next step may be to lay out these ideas in a more systematic manner.

Discussion: Planning for Moving Forward on New Ethics Subcommittee Activities

Robert Hood, PhD, PHEC Chair
Florida Department of Health

During this session, discussion continued with regard to ways in which the Ethics Subcommittee can be effective as it moves forward. Dr. Hood began the discussion by acknowledging the wealth of ideas and options available to the subcommittee in terms of strategic planning and building upon existing work.

One way to approach operationalizing public consultation is to survey the needs of state and local health departments. The proposed public health ethics consortium may be able to take on as its focus the relationship between public health ethics and what is occurring at the local level. The survey may be one way to bridge the gap between academia and local action. The subcommittee could separate into a workgroup that focuses on designing this survey.

Roger Bernier described a series of grants that were distributed to six state and local health departments tasked with engaging the public on a pandemic influenza-related policy question. The well-documented results of this process would be an interesting model to build upon. These particular health departments might be receptive audiences for new initiatives in public engagement.

As the subcommittee seeks to plan future directions, Dr. Frieden's list of priorities is an excellent guideline. A survey of health departments in particular would fall neatly into the category of state and local support, as well as surveillance (e.g., gathering data that would drive decisions). As a tool for targeting ethical issues that are causing state and local health departments to struggle with addressing the main causes of a disease, the survey may be able to differentiate between highly contentious issues and issues for which the Ethics Subcommittee and PHEC could provide practical resources.

Some suggestions for survey topics include:

- What ethical issues present the greatest challenges?
- What practical tools would be of benefit to the health departments in dealing with ethical issues?
- What best practices exist that could be built upon?
- In the past year, health departments have been encouraged to engage the public, but were not given specific guidance on how to approach this process. In the absence of guidance, how did the health departments fare? What methods did they employ?
- Are there existing case studies where health departments specifically dealt with ethical dilemmas?
- Would social media be an effective tool for building partnerships between academia and the practice community?

There was interest expressed in developing capacity within state and local health departments for integrating ethics. Collaboration with the new CDC Office of State, Tribal, Local, and Territorial Support on this effort would be important. Members of this new office may be available to address the subcommittee and share their perspectives in future meetings.

Dr. Barrett pointed out that PHEC is currently focusing on the development of cases studies and that members of the Ethics Subcommittee may be interested in collaborating on this effort. In order to focus on the development of practical tools, it was suggested that perhaps a simple handbook, presenting an ethics framework against which to evaluate case studies may be more useful than a compilation of case studies. This is a means of simplifying the presentation of information to practitioners who may not have time to sift through a large amount of information.

Structured discussions using case studies are a traditional way to demonstrate ethics. A casebook is most effective when there is a facilitator to lead discussion.

Other potential topics of interest for the committee to address include:

- Development of an evaluation strategy
- An examination of how the Public Health Code of Ethics applies to the work of CDC
- Development of options for building workforce capacity in ethics
- Assisting in the procedural issues involved in accreditation of health departments
- Exploring use of new social media, such as *Facebook*, as a tool for building capacity in public health ethics

Global health issues, an item on the list of priorities, may be more difficult to address and are, therefore, probably not the best focus for the Ethics Subcommittee. In the process of developing evaluation metrics, an awareness of global health issues may result in topical priorities being addressed.

Based on the discussions about potential activities, Dr. Barrett suggested that a possible next step would be to convene a workgroup focused on developing a strategy for supporting state and local health departments and for exploring methods of evaluating the value and impact of CDC's ethics activities. This workgroup could explore the development of a survey of state and local health departments. Ethics Subcommittee members Leslie Wolf and Robert Hood agreed to participate in the workgroup.

A workgroup to address the development of case studies was also organized. Ethics Subcommittee members who joined this group included Lavera Crawley, Jennifer Prah Ruger, Norman Daniels, and Ruth Gaare Bernheim.

As there are potential areas of overlap and collaboration, the two workgroups will coordinate their efforts whenever possible. Both workgroups will be strongly supported by members from the internal CDC public health ethics committee, PHEC.

Public Comment

At 11:43 am, Dr. Robert Hood opened the floor to public comment. Two books of topical interest to the subcommittee were suggested:

- Successful Societies: How Institutions and Culture Affect Health*, Peter A. Hall (editor) and Michèle Lamont (editor), 2009.
- Health and Social Justice*, Jennifer Prah Ruger, 2010.
-

Procedural Issues and Meeting Wrap-Up

Robert Hood, PhD, PHEC Chair
Florida Department of Health

The subcommittee was reminded to complete their meeting evaluation forms. The two new workgroups will meet before the next meeting scheduled for June 17-18, 2010. The State and Local Support/Evaluation Workgroup shall make an effort to draft a survey for the subcommittee to review, and also propose some suggestions for possible evaluation models which can be discussed at the next meeting. The Case Studies Workgroup will identify one or two potential topics for case studies and will present an outline of each. The workgroup will also consider the types of vehicles with which to communicate these case studies.

Drs. Popovic and Briss thanked the subcommittee for a very productive meeting and stimulating conversation. The work of this meeting will be conveyed to Dr. Frieden and any response will be relayed to the subcommittee members.

With no further business posed or discussion raised, the meeting was adjourned at 11:52 AM.



Certification

I hereby certify that to the best of my knowledge, the foregoing minutes of the February 18-19, 2010 Ethics Subcommittee meeting are accurate and complete.

Date

Robert Hood, PhD
Ethics Subcommittee Chair

Attachment 1: List of Meeting Attendees

February 18, 2010

Ethics Subcommittee, Advisory Committee to the Director

Ruth Gaare Bernheim, University of Virginia
Vivian Berryhill, ACD, National Coalition of Pastors' Spouses (phone)
Norman Daniels, Harvard University (phone)
Robert Hood, Ethics Subcommittee Chair, Florida Department of Health
Bernard Lo, University of California, San Francisco (phone)
LaVera Marguerite Crawley, Stanford University Center for Biomedical Ethics
Jennifer Prah Ruger, Yale University
Pamela Sankar, University of Pennsylvania Department of Medical Ethics

Centers for Disease Control and Prevention

Drue Barrett, Designated Federal Officer, Ethics Subcommittee	Mary Jenkins (phone)
Francisco Alvarado	Kimberly Lane
Fred Angulo	Lisa M. Lee
Mary Ari	Bryan Lindsey
Elise Beltrami	Aun Lor
Constance Bonds	Hugh Mainzer
Scott Campbell	Daniel McDonald
Cheryl Coble	Fred Murphy
Joanne Cono	Mary Neumann (phone)
Xiaohong Davis	Leonard Ortmann
Barbara Ellis	Radha Pennotti
Lindsay Feldman	John Piacentino (phone)
Karen Gavin (phone)	Lauretta Pinckney (phone)
Neelam D. Ghiya	Tanja Popovic
Sara Giordano	Cheri Rice
Gail Horlick	Anne Sowell (phone)
	Antonia Spadaro

Members of the Public

Chad F. Slioper, Global Health Law and Policy, Emory University School of Law

February 19, 2010

Ethics Subcommittee, Advisory Committee to the Director

Ruth Gaare Bernheim, University of Virginia
Vivian Berryhill, ACD Member, National Coalition of Pastors' Spouses (phone)
LaVera Marguerite Crawley, Stanford University
Norman Daniels, Harvard University (phone)
Robert Hood, Chair, Florida Department of Health
Jennifer Prah Ruger, Yale University
Pamela Sankar, University of Pennsylvania
Leslie Wolf, Georgia State University

Centers for Disease Control and Prevention

Drue Barrett, Designated Federal Officer,
Ethics Subcommittee
Mary Ari
Fred Angulo
Elise Beltrami
Roger Bernier
Constance Bonds (phone)
Peter Briss
Scott Campbell
Joanne Cono
Xiaohong Davis
Barbara Ellis
Lindsay Feldman
Genny Gallagher
Neelam D. Ghiya
Sara Giordano
Sean D. Griffiths
Gail Horlick
Kimberly Lane
Lisa M. Lee
Bryan Lindsey (phone)
Aun Lor
Hugh Mainzer (phone)
Josephine Malilay (phone)
Daniel McDonald
Leonard Ortmann
Radha Pennotti
John Piacentino (phone)
Lauretta Pinckney (phone)
Tanja Popovic
Anne Sowell (phone)
Antonia Spadaro